

REMARKS

Applicants respectfully request that should additional fees or a credit be associated with the filing of this paper, the additional fees or credit can be charged or credited to the undersigned Attorney's Deposit Account 10-0100.

Claims 35, 36 and 37 are added.

Claims 14, 15, 31 and 35 - 37 are presented for reconsideration or examination on the merits.

Claim 14 is rejected under 35 USC § 102(b) as allegedly being anticipated by El-Khalaty et al.

Claims 14, 15 and 31 are rejected under 35 USC § 102 as allegedly being anticipated by Rabarisoa et al.

Applicants respectfully traverse the rejections.

Applicant claims in new claims 35-37 a lipid fraction extract from *R. regia* whole fruit, which lipid fraction *R. regia* whole fruit is not disclosed in El-Khalaty et al. and/or Rabarisoa et al. On full and fair reading, El-Khalaty et al. and Rabarisoa et al. teach away from the specifically claimed lipid fraction, and also teach away from *R. Regia* whole fruit.

The stated grounds for the rejections conflates "oil" with "lipid fraction", and also conflates "kernel oil" with "whole fruit extract", and also conflates different genus and species of nuts and fruits. These conflated elements are art cognizably structurally and chemically distinguished, as further discussed herein. The stated grounds for the rejections also conflates "pharmaceutical composition" with a "food seed oil".

Claim 35 identifies the invention as a “pharmaceutical composition” that is a novel “lipid fraction” “extract” of “whole fruit” of a certain genus and species, viz. *R. regia*, wherein the C16:1 fraction is operably in present percentages of “1.5-20”. El-Khalaty et al. does not disclose *R. regia* whole fruit or the lipid fraction. Therefore, El-Khalaty et al. fails to suggest this lipid fraction. El-Khalaty et al. is inoperable because the claimed lipid fraction cannot be obtained from the El-Khalaty et al. the seed or kernel. This inoperability is manifest in a reading of the El-Khalaty et al. Table. The El-Khalaty et al. Table was discussed in extenso in in prior Remarks, which Remarks are incorporated herein by reference.

That is, there is no prior art teaching, disclosure or direction to the claimed lipid fraction.

There is no prior art disclosure or suggestion to provide a *R. regia* whole fruit extract pharmaceutical composition. There is no prior art disclosure claimed specific lipid fraction, particularly the palmitoleic acid component of 1.5 to 20%.

Applicants submit herewith as Exhibit A a comparison of fatty acid (%) of palm oil and palm kernel oil obtained from different genus and species, namely *Elaeis guineensis* and *Roystonea regia*. The Exhibit A prior art published results confirm what El-Khakaty et al. teaches, namely that the palmitoleic acid C16:1 component is absent or present in trace amounts in the kernel oil . The Exhibit A prior art thereby supports the novel lipid fraction as presently claimed, particularly the C16:1 lipid fraction component of 1.5 – 20.0% (claims 35-37). The Exhibit A art published results also undercut the Office Action conflation of “kernel” with “whole fruit”, and *R. regia*” with other genus and species of fruits and kernels.

The present claims claim a pharmaceutical composition consisting of the hydrolyzed extract obtained from the whole fruit of *Roystonea regia* (claim 36). El-Khalaty et al. does not mention a pharmaceutical composition, but just oil extracted from the seeds and only for conventional food use. El-Khalaty et al. discloses the proportions of fatty acids in seed oil, which fatty oils are distinctly different from that presently claimed. El-Khalaty et al. does not suggest that a person skilled in the art could readily deduce that a pharmaceutical composition can consist of a hydrolyzed extract from the whole fruit of *R. regia*. Rabarisoa et al. also discusses oil useful in food production, and again fails to recognize or suggest a pharmaceutical composition, let alone the presently claimed composition.

Claim 36 claims that the pharmaceutical composition is a novel specific lipid fraction obtained after the chemical hydrolysis of glycerides, which also differs from the El-Khalaty et al. paper related to the seed oil of *Roystonea regia*.

El-Khalaty et al. and Rabarisoa et al. neither report a pharmaceutical composition nor a pharmacological effect or activity of any composition, but rather conventional food seed oils. The rejection conjures that the pharmaceutical and composition is inherent is Rabarisoa et al. This conjecture is undercut by the foregoing reasons and further because claims 35-37 claim an operable lipid fraction not disclosed by Rabarisoa et al. For example, claims 35-37 claim an operable lipid component of 1.5-2.0% C:16.1, whereas Rabarisoa et al. discloses no C16:1 component. The conjecture of the same inherent

pharmaceutical composition in Rabariosa et al. is therefore wholly undercut by a reading of Rabariosa et al.

The presently claimed lipid fraction has a different composition from those reported by El-Khalaty et al. and Rabarisoa. El-Khalaty et al., on fair reading, is a simple description of food seed oil, and undercut a pharmaceutical composition or a composition having any active ingredient or pharmacological operability. In addition, the El-Khalaty et al. fatty acids and proportions are distinctly different from those claimed. The claimed extract fatty acids are well beyond the limits of the El-Khalaty et al. composition: palmitoleic acid in an amount of 1.5 - 20 % as claimed in contradistinction to trace amounts in El-Khalaty et al. (see e.g. claim 35); and oleic acid including both linoleic and linolenic acids in a total amount of 3.0 – 50.0 % as claimed compared with 53.1% in El-Khalaty et al. (see claim 37).

Rabarisoa et al. and El-Khalaty et al. importantly, teach separating the seeds from the epicarp. Rabarisoa et al. and El-Khalaty et al. thereby teach away from the whole fruit and away from the present invention. Rabariosa et al. does not report the presence of the following acids: palmitoleic (C16:1), caprillic (C8:0) and capric (C10:0), which combination of fatty acids are presently claimed² (e.g. claims 15 and 35-37). Rabarisoa et al. cannot, as a matter of law or logic, be held to anticipate the claims.

The presently claimed lipid fraction composition is an extract of a whole fruit of a specific genus and species, and “consists of” lipid fraction extract “product produced by the hydrolysis of glycerides” (claim 36). The compositions

of oils extracted from seeds and whole fruits are far removed from each other and cannot in light of the prior art be conflated. Further, the “kernel oil” is very different from the “palm oil” obtained from pericarp of the fruit (see Exhibit A). *Roystonea regia* and *Elaeis guineensis* provides two types of different oils: the palm oil from the pericarp and the palm kernel oil from the nut (the endosperm). These art cognizable distinctions in oils from the pericarp and seed undercut the conflation of the rebuttal of the Office Action.

Rabarisoa et al. discusses different species as well as different parts of the fruits that provide different results. This fact undercuts the Office Action rebuttal. Rabarisoa et al. compares the fatty acid composition of pericarp oils and kernel oils from different species. Rabarisoa et al., with few exceptions, discloses that palm kernel oils are essentially lauric, and due to the high saturation of the fat, the kernel oil is semi-fluid or solid at 18°C. This further undercuts reading the presently claimed hydrolyzed extract with Rabarisoa et al., and further undercuts the inherent pharmaceutical composition.

Moreover, the present invention is related to *Roystonea regia* fruit, not to *Cocos nucifera* fruit. *C. nucifera* fruit is art cognizably different from the *R. regia* fruit, and indeed is very different from any other fruit of the *Arecaceae* family. Scott Zona teaches that the fruits of *Roystonea* genus are composed of a smooth pericarp that encloses an oily, fleshy mesocarp and a brittle to hard endocarp. The endocarp is spheroid or oblong with a small acute process at the base and encloses a single seed.³ The *Roystonea* genus seed and fruit differences are well established. Conflating genus, species, whole fruit, pericarp, and endocarp

